

109TH CONGRESS  
2D SESSION

# S. 3128

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MAY 25, 2006

Mr. BURR (for himself, Mr. NELSON of Nebraska, and Mr. ROBERTS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “National Uniformity  
5       for Food Act of 2006”.

6       **SEC. 2. NATIONAL UNIFORMITY FOR FOOD.**

7       (a) NATIONAL UNIFORMITY.—Section 403A of the  
8       Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–  
9       1) is amended—

1           (1) in subsection (a)(4), by striking “or” at the  
2       end;

3           (2) in subsection (a)(5), by striking the period  
4       and inserting “, or”;

5           (3) in subsection (a), by inserting after para-  
6       graph (5) the following:

7           “(6) any requirement for a food described in  
8       section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),  
9       402(c), 404, 406, 409, 512, or 721(a), that is not  
10      identical to the requirement of such section.”; and

11          (4) by adding at the end the following:

12      “(c)(1) For purposes of subsection (a)(6) and section  
13   403B, the term ‘identical’ means that the language under  
14   the laws of a State or a political subdivision of a State  
15   is substantially the same language as the comparable pro-  
16   vision under this Act and that any differences in language  
17   do not result in the imposition of materially different re-  
18   quirements. For purposes of subsection (a)(6), the term  
19   ‘any requirement for a food’ does not refer to provisions  
20   of this Act that relate to procedures for Federal action  
21   under this Act.

22      “(2) For purposes of subsection (a)(6), a State or  
23   political subdivision of a State may enforce a State law  
24   that contains a requirement that is identical to a require-  
25   ment in a section of Federal law referred to in subsection

1 (a)(6) if the Secretary has promulgated a regulation or  
 2 adopted a final guidance relating to the requirement and  
 3 the State applies the State requirement in a manner that  
 4 conforms to the regulation or guidance.

5 “(3) If the Secretary has not promulgated a regula-  
 6 tion or adopted final guidance relating to a requirement  
 7 in a section of Federal law referred to in subsection (a)(6),  
 8 a State or political subdivision of a State may enforce a  
 9 policy, such as a State regulation or an administrative de-  
 10 cision, that is based on a State law that contains a require-  
 11 ment that is identical to a requirement in a section of Fed-  
 12 eral law referred to in subsection (a)(6).

13 “(4) If the Secretary has considered a proposal for  
 14 a regulation or final guidance relating to a requirement  
 15 in a section of Federal law referred to in subsection (a)(6)  
 16 and has, after soliciting public comment, made a deter-  
 17 mination not to promulgate such regulation or adopt such  
 18 guidance, which determination is published in the Federal  
 19 Register, a State or political subdivision of a State may  
 20 not enforce any requirements in State law that are policies  
 21 rejected by the Secretary through such determination.”.

22 (b) UNIFORMITY IN FOOD SAFETY WARNING NOTI-  
 23 FICATION REQUIREMENTS.—Chapter IV of such Act (21  
 24 U.S.C. 341 et seq.) is amended—

1           (1) by redesignating sections 403B and 403C  
2           as sections 403C and 403D, respectively; and

3           (2) by inserting after section 403A the fol-  
4           lowing new section:

5   **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-**  
6                           **FICATION REQUIREMENTS.**

7           “(a) UNIFORMITY REQUIREMENT.—

8                   “(1) IN GENERAL.—Except as provided in sub-  
9           sections (c) and (d), no State or political subdivision  
10          of a State may, directly or indirectly, establish or  
11          continue in effect under any authority any notifica-  
12          tion requirement for a food that provides for a warn-  
13          ing concerning the safety of the food, or any compo-  
14          nent or package of the food, unless such a notifica-  
15          tion requirement has been prescribed under the au-  
16          thority of this Act and the State or political subdivi-  
17          sion notification requirement is identical to the noti-  
18          fication requirement prescribed under the authority  
19          of this Act.

20                   “(2) DEFINITIONS.—For purposes of paragraph  
21          (1)—

22                           “(A) the term ‘notification requirement’ in-  
23          cludes any mandatory disclosure requirement  
24          relating to the dissemination of information  
25          about a food by a manufacturer or distributor

1 of a food in any manner, such as through a  
2 label, labeling, poster, public notice, advertising,  
3 or any other means of communication, except  
4 as provided in paragraph (3);

5 “(B) the term ‘warning’, used with respect  
6 to a food, means any statement, vignette, or  
7 other representation that indicates, directly or  
8 by implication, that the food presents or may  
9 present a hazard to health or safety; and

10 “(C) a reference to a notification require-  
11 ment that provides for a warning shall not be  
12 construed to refer to any requirement or prohi-  
13 bition relating to food safety that does not in-  
14 volve a notification requirement.

15 “(3) CONSTRUCTION.—Nothing in this section  
16 shall be construed to prohibit a State from con-  
17 ducting the State’s notification, disclosure, or other  
18 dissemination of information, or to prohibit any ac-  
19 tion taken relating to an inspection, mandatory re-  
20 call, civil administrative order, embargo, detention  
21 order, or court proceeding involving food adultera-  
22 tion under a State statutory requirement identical to  
23 a food adulteration requirement under this Act.

24 “(b) REVIEW OF EXISTING STATE REQUIRE-  
25 MENTS.—

1           “(1) EXISTING STATE REQUIREMENTS; DEFER-  
2       RAL.—Any requirement that—

3           “(A)(i) is a State notification requirement  
4       that expressly applies to a specified food or food  
5       component and that provides for a warning de-  
6       scribed in subsection (a) that does not meet the  
7       uniformity requirement specified in subsection  
8       (a); or

9           “(ii) is a State food safety requirement de-  
10      scribed in section 403A(a)(6) that does not  
11      meet the uniformity requirement specified in  
12      that paragraph; and

13          “(B) is in effect on the date of enactment  
14      of the National Uniformity for Food Act of  
15      2006, shall remain in effect for 180 days after  
16      that date of enactment.

17          “(2) STATE PETITIONS.—With respect to a  
18      State notification or food safety requirement that is  
19      described in paragraph (1), the State may petition  
20      the Secretary for an exemption or a national stand-  
21      ard under subsection (c). If a State submits such a  
22      petition within 180 days after the date of enactment  
23      of the National Uniformity for Food Act of 2006,  
24      the notification or food safety requirement shall re-  
25      main in effect in accordance with subparagraph (C)

of paragraph (3), and the time periods and provisions specified in subparagraphs (A) and (B) of such paragraph shall apply in lieu of the time periods and provisions specified in subsection (c)(3) (but not the time periods and provisions specified in subsection (d)(2)).

“(3) ACTION ON PETITIONS.—

“(A) PUBLICATION.—Not later than 270 days after the date of enactment of the National Uniformity for Food Act of 2006, the Secretary shall publish a notice in the Federal Register concerning any petition submitted under paragraph (2) and shall provide 180 days for public comment on the petition.

“(B) TIME PERIODS.—Not later than 360 days after the end of the period for public comment, the Secretary shall take final agency action on the petition.

“(C) ACTION.—

“(i) IN GENERAL.—With respect to a State that submits to the Secretary a petition in accordance with paragraph (2), the notification or food safety requirement involved shall remain in effect during the period beginning on the date of enactment of

the National Uniformity for Food Act of 2006 and ending on the applicable date under subclause (I) or (II), as follows:

“(I) If the petition is denied by the Secretary, the date of such denial.

“(II) If the petition is approved by the Secretary, the effective date of the final rule that is promulgated under subsection (c) to provide an exemption or national standard pursuant to the petition, except that there is no applicable ending date under this subparagraph for a provision of State law that is part of such State requirement in any case in which the final rule does not establish any condition regarding such provision of law.

“(ii) NONCOMPLIANCE OF SECRETARY REGARDING TIMEFRAMES.—

“(I) JUDICIAL REVIEW.—The failure of the Secretary to comply with any requirement of subparagraph (A) or (B) shall constitute final agency action for purposes of judicial review. If the court conducting the re-



view determines that the Secretary has failed to comply with the requirement, the court shall order the Secretary to comply within a period determined to be appropriate by the court.

“(II) STATUS OF STATE REQUIREMENT.—With respect to a State that submits to the Secretary a petition in accordance with paragraph (2), if the Secretary fails to take final agency action on the petition within the period that applies under subparagraph (B), the notification or food safety requirement involved remains in effect in accordance with clause (i).

“(c) EXEMPTIONS AND NATIONAL STANDARDS.—

“(1) EXEMPTIONS.—Any State may petition the Secretary to provide by regulation an exemption from section 403A(a)(6) or subsection (a), for a requirement of the State or a political subdivision of the State. The Secretary may provide such an exemption, under such conditions as the Secretary may impose, for such a requirement that—

1           “(A) protects an important public interest  
2           that would otherwise be unprotected, in the ab-  
3           sence of the exemption;

4           “(B) would not cause any food to be in  
5           violation of any applicable requirement or prohi-  
6           bition under Federal law; and

7           “(C) would not unduly burden interstate  
8           commerce, balancing the importance of the pub-  
9           lic interest of the State or political subdivision  
10          against the impact on interstate commerce.

11          “(2) NATIONAL STANDARDS.—Any State may  
12          petition the Secretary to establish by regulation a  
13          national standard respecting any requirement under  
14          this Act or the Fair Packaging and Labeling Act  
15          (15 U.S.C. 1451 et seq.) relating to the regulation  
16          of a food.

17          “(3) ACTION ON PETITIONS.—

18                 “(A) PUBLICATION.—Not later than 30  
19                 days after receipt of any petition under para-  
20                 graph (1) or (2), the Secretary shall publish  
21                 such petition in the Federal Register for public  
22                 comment during a period specified by the Sec-  
23                 retary.

24                 “(B) TIME PERIODS FOR ACTION.—Not  
25                 later than 60 days after the end of the period

1           for public comment, the Secretary shall take  
2           final agency action on the petition or shall in-  
3           form the petitioner, in writing, the reasons that  
4           taking the final agency action is not possible at  
5           that time, the date by which the final agency  
6           action will be taken, and the final agency action  
7           that will be taken or is likely to be taken. In  
8           every case, the Secretary shall take final agency  
9           action on the petition not later than 120 days  
10          after the end of the period for public comment.

11                 “(C) EXPEDITED CONSIDERATION.—The  
12          Secretary shall expedite the consideration of  
13          any petition under paragraphs (1) or (2) that  
14          involves a request for a notification requirement  
15          for a food that provides a warning where the  
16          health effect to be addressed by the warning re-  
17          lates to cancer or reproductive or birth defects  
18          or is intended to provide information that will  
19          allow parents or guardians to understand, mon-  
20          itor, or limit a child’s exposure to cancer-caus-  
21          ing agents or reproductive or developmental  
22          toxins or will allow pregnant women to under-  
23          stand, monitor, or limit their exposure to fetal  
24          development toxins.

1           “(4) JUDICIAL REVIEW.—The failure of the  
 2       Secretary to comply with any requirement of this  
 3       subsection shall constitute final agency action for  
 4       purposes of judicial review. If the court conducting  
 5       the review determines that the Secretary has failed  
 6       to comply with the requirement, the court shall  
 7       order the Secretary to comply within a period deter-  
 8       mined to be appropriate by the court.

9       “(d) IMMINENT HAZARD AUTHORITY.—

10           “(1) IN GENERAL.—A State may establish a re-  
 11       quirement that would otherwise violate section  
 12       403A(a)(6) or subsection (a), if—

13           “(A) the requirement is needed to address  
 14       an imminent hazard to health that is likely to  
 15       result in serious adverse health consequences or  
 16       death;

17           “(B) the State has notified the Secretary  
 18       about the matter involved and the Secretary  
 19       has not initiated enforcement action with re-  
 20       spect to the matter;

21           “(C) a petition is submitted by the State  
 22       under subsection (c) for an exemption or na-  
 23       tional standard relating to the requirement not  
 24       later than 30 days after the date that the State

1 establishes the requirement under this sub-  
2 section; and

3 “(D) the State institutes enforcement ac-  
4 tion with respect to the matter in compliance  
5 with State law within 30 days after the date  
6 that the State establishes the requirement  
7 under this subsection.

8 “(2) ACTION ON PETITION.—

9 “(A) IN GENERAL.—The Secretary shall  
10 take final agency action on any petition sub-  
11 mitted under paragraph (1)(C) not later than 7  
12 days after the petition is received, and the pro-  
13 visions of subsection (c) shall not apply to the  
14 petition.

15 “(B) JUDICIAL REVIEW.—The failure of  
16 the Secretary to comply with the requirement  
17 described in subparagraph (A) shall constitute  
18 final agency action for purposes of judicial re-  
19 view. If the court conducting the review deter-  
20 mines that the Secretary has failed to comply  
21 with the requirement, the court shall order the  
22 Secretary to comply within a period determined  
23 to be appropriate by the court.

24 “(3) DURATION.—If a State establishes a re-  
25 quirement in accordance with paragraph (1), the re-

1        requirement may remain in effect until the Secretary  
 2        takes final agency action on a petition submitted  
 3        under paragraph (1)(C).

4        “(e) NO EFFECT ON PRODUCT LIABILITY LAW.—  
 5        Nothing in this section shall be construed to modify or  
 6        otherwise affect the product liability law of any State.

7        “(f) NO EFFECT ON CERTAIN STATE LAW.—Nothing  
 8        in this section or section 403A relating to a food shall  
 9        be construed to prevent a State or political subdivision of  
 10       a State from establishing, enforcing, or continuing in ef-  
 11       fect a requirement relating to—

12                “(1) freshness dating, open date labeling, grade  
 13        labeling, a State inspection stamp, religious dietary  
 14        labeling, organic or natural designation, returnable  
 15        bottle labeling, unit pricing, a statement of geo-  
 16        graphic origin, or dietary supplements; or

17                “(2) a consumer advisory relating to food sani-  
 18        tation that is imposed on a food establishment, or  
 19        that is recommended by the Secretary, under part  
 20        3–6 of the Food Code issued by the Food and Drug  
 21        Administration and referred to in the notice pub-  
 22        lished at 64 Fed. Reg. 8576 (1999) (or any cor-  
 23        responding similar provision of such a Code).

24        “(g) DEFINITIONS.—In section 403A and this sec-  
 25        tion:

1           “(1) The term ‘requirement’, used with respect  
2           to a Federal action or prohibition, means a manda-  
3           tory action or prohibition established under this Act  
4           or the Fair Packaging and Labeling Act (15 U.S.C.  
5           1451 et seq.), as appropriate, or by a regulation  
6           issued under or by a court order relating to, this Act  
7           or the Fair Packaging and Labeling Act, as appro-  
8           priate.

9           “(2) The term ‘petition’ means a petition sub-  
10          mitted in accordance with the provisions of section  
11          10.30 of title 21, Code of Federal Regulations, con-  
12          taining all data and information relied upon by the  
13          petitioner to support an exemption or a national  
14          standard.”.

15          (c) CONFORMING AMENDMENT.—Section 403A(b) of  
16          such Act (21 U.S.C. 343–1(b)) is amended by adding after  
17          and below paragraph (3) the following:

18          “The requirements of paragraphs (3) and (4) of sec-  
19          tion 403B(c) shall apply to any such petition, in the same  
20          manner and to the same extent as the requirements apply  
21          to a petition described in section 403B(c).”.

22          **SEC. 3. CONDITIONS.**

23          The amendments made by this Act take effect only  
24          if the Secretary of Health and Human Services certifies  
25          to the Congress, after consultation with the Secretary of

1 Homeland Security, that the implementation of such  
2 amendments will pose no additional risk to the public  
3 health or safety from terrorists attacks relating to the food  
4 supply.

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